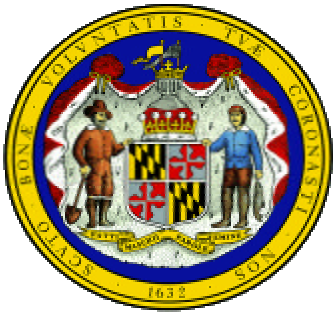
An Analysis and Evaluation of Certificate of Need Regulation in Maryland

Acute Inpatient Obstetric Services

Summary and Analysis of Public Comments and Staff Recommendation



MARYLAND HEALTH CARE COMMISSION

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An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Acute Inpatient Obstetric Services

I. Introduction

The Maryland Health Care Commission's working paper, titled *An Analysis and Evaluation of Certificate of Need Regulation in Maryland: Acute Inpatient Obstetric Services*, was developed as one in a series of working papers examining major policy issues of the Certificate of Need process, as required by House Bill 995 (1999). The paper provides the basis for public comment on a series of potential alternative regulatory strategies:

Option 1:	Maintain Existing Certificate of Need Program Regulation
Option 2:	Expanded Certificate of Need Program Regulation
Option 3:	Maintain Existing Certificate of Need Program Regulation, with Regional Need Projection
Option 4:	Partial Deregulation-Create CON Exemption Process for New Obstetric Service
Option 5:	Deregulate Obstetric Services from CON Review, Require Data Reporting
Option 6:	Deregulate Obstetric Services from CON Review, Create Licensure Standards
Option 7:	Deregulate Obstetric Services from CON Review Requirement

The objective of this working paper is to provide information to the Commission on whether changes are needed with respect to CON regulation of hospital obstetric services. The working paper was released for public comment at the July 21, 2000 meeting of the Maryland Health Care Commission. As of the date of this paper, fifteen (15) written comments have been received. Those public comments are summarized in Part II. A staff analysis of the public comments is provided in Part III.

II. Summary of Public Comments[1]

Anne Arundel Medical Center (AAMC) states that Maryland's obstetric services are accessible, available, cost effective and of high quality, and that there is no reason to replace the CON program for obstetrics. Anne Arundel states that no case has been made to change the current system, and that change for the sake of change is inappropriate. Anne Arundel also suggests that any radical restructuring of the CON process would require some relief from the commitment not to increase rates to pay associated debt costs

[1] A complete set of the written copies received on the Acute Inpatient Obstetrical Services Working Paper may be obtained by contacting the Division of Health Resources at (410) 764-3232.

– "the pledge" - that has accompanied almost all major capital projects in Maryland over the past 15 years.

Carroll County General Hospital (CCGH) supports maintaining the existing CON program regulation, which is Option 1.

The Department of Health and Mental Hygiene's Center for Maternal and Child Health (DHMH/CMCH) supports the CON program for obstetric services. Their letter states that spreading admissions over more hospitals may lower the quality of care due to lack of experience, given the complexity of care required for high risk situations. They also recommend close coordination between policies for obstetric services, NICU services and neonatology services.

Dimensions Healthcare System (DHS) supports the continuation of the CON program for obstetric services.

The joint letter from Doctors Community Hospital, North Arundel Hospital, Suburban Hospital and University of Maryland Medical System supports Option 7 calling for elimination of the CON program with no replacement, and describes the disadvantages of not being full service hospitals.

Garrett County Memorial Hospital (GCMH) states that current regulations regarding obstetric services have helped assure appropriate service distribution throughout Maryland, and that no change is needed. Obstetric services are very important to this hospital and its community, even though volumes are low and the cost of maintaining the service is relatively high, since the 30 minute travel time standard would not be met for a number of Maryland and West Virginia residents without it.

Greater Baltimore Medical Center's (GBMC) letter does not support one option over another, and expresses general uncertainty about Certificate of Need as a mechanism to meet changing health care needs. GBMC states that elimination or radical restructuring of the CON process should be accompanied by relief from the "pledge" made by hospitals to pay debt costs from capital projects involving obstetric services. GBMC also rejects Option 3 that would replace jurisdictional need projections with regional need projections.

The Health Services Cost Review Commission (HSCRC) supports the paper's conclusion that one significant impact of deregulation could be increased costs to existing providers and/or to the State's health care system due to declining volume at existing services and increased competition for staff and state-of-the-art facilities.

Holy Cross Hospital (HCH) supports the current system of CON coverage for obstetric services. HCH supports the need for continued regulatory oversight to assure a systemic planning process for the allocation of health services and resources to meet public needs and provide balance in the delivery system. Holy Cross states that the cost implications of adding additional capacity would not be in the best interest of the community.

Johns Hopkins Health System (JHHS), which includes three acute care hospitals, supports Option 1, to maintain the current CON regulation.

LifeBridge Health (LBH), which includes two acute care hospitals, recommends that the MHCC continue to require CON for the creation of new obstetric services. LifeBridge also supports regional rather than jurisdictional need projections, as described in Option 3, but only with a change to allow the relocation of an entire service, rather than the splitting of a service to create a new service.

The Maryland Institute for Emergency Medical Services Systems (MIEMSS) provided comments clarifying the role of MIEMSS in obstetric services.

MedStar Health (MSH), which includes four acute care hospitals in Maryland (as well as two in the District of Columbia), supports the CON model of regulation for implementing health policies, unless it can be determined that the process no longer serves a compelling public purpose. The letter states that the current Certificate of Need program regulations (Option 1) represent an appropriate balance of public and private interests.

Montgomery County's Department of Health and Human Services (MCDHHS) requests that the State Health Plan include a section on population-based health planning, to include infant mortality rates by hospital and/or by county.[2]

St. Agnes Hospital (SAH) states that the CON program hinders the hospital's ability to respond to the changing needs of the communities served. St. Agnes supports Option 6, replacing CON regulations with licensure standards for all hospital services, including obstetric services, to include performance standards, mandatory reporting of outcomes, and a minimum volume threshold as a standard for operating an obstetric service.

III. Staff Analysis of Public Comments

A. Option 1 – Maintain Existing Certificate of Need Program Regulation, and Option 7 – Deregulation of Obstetrics from Certificate of Need Review

The Certificate of Need program emphasizes prospective statewide planning with the interests of the public in mind. It requires that certain actions by health care facilities, deemed by the General Assembly to be of greatest public importance, obtain approval in a public process with a demonstration that the new action, whether a new service or facility or a closure, would have a positive impact on the system.

[2] The Department of Health and Mental Hygiene is preparing a Health Improvement Plan for Maryland. This HIP is a product of Healthy Maryland – Project 2010, Maryland's response to the nationwide Healthy People initiative. The HIP is designed to provide a framework for recommendations for improving the health of Marylanders, and contains a section specific to Montgomery County, including county-specific infant mortality rates.

The working paper's deregulation option would result in elimination of the CON requirement for obstetric services. No role would remain for the Commission to review new obstetric services for their impact on the system of hospital obstetric care in the area, or to review service closures. Market forces would guide access decisions. Competition would play a larger role in cost and quality than they do now. The working paper and the public comments received address both the advantages and disadvantages of the current CON program and of deregulation, and are addressed below.

Public comments in support of CON regulation describe the program's benefits, including assuring that health services development is consistent with state health goals (such as financial and geographic access), allowing for thoughtful planned growth in capacity, considering public interests, using a prospective planning process to maintain reasonable access to appropriate services, insuring optimal quality among providers, and requiring that health care providers are accountable to the public (CCGH; GBMC; JHHS; HCH; MSH). Some comments note that the CON program enhances and supports the State's objective of ensuring that new services are developed as needed based on publicly developed criteria (LBH; HCH). Other comments state that CON regulation of the full spectrum from routine to specialized perinatal services allows for better private sector support of public policy objectives. Controlling the supply and avoiding potential unnecessary duplication of services serves a compelling public interest. (MSH). AAMC suggests that the existing CON regulations currently permit any hospital to present a case that access to obstetric services is inappropriately denied, and that an applicant has the financial and other resources necessary to meet that unmet need.

The joint letter from Doctors Community Hospital, North Arundel Hospital, Suburban Hospital and University of Maryland Medical System describes the current CON program's disadvantages, including that the program precludes a free market approach to new obstetric services, and does not allow individual hospitals to make decisions to add obstetric services that would be in the best interest of the hospital and its community. Their letter states that the obstetrics is a basic community service, and that CON requirements prevent their hospitals from being full service hospitals, from meeting the full needs of their patient populations, and from competing on an even basis with their competitors. These hospitals provide other services for women, but not obstetrics. The letter states that the quality of care they provide in their women's health programs would improve if obstetrics services were available, and that prevention and outreach programs would be more cost effective.

This joint letter of public comment describes two reasons for eliminating CON laws for obstetric services. First, the CON program was designed to control excessive hospital costs in a time of cost-based reimbursement, when health care inflation was high. For example, hospitals could spend money on large capital projects without financial risk, and expect those costs to be reimbursed by payers. According to this letter, the influence of managed care has all but eliminated cost-based reimbursement. Second, these hospitals argue that the CON program was designed to control excessive utilization under the

assumption that supply creates demand. But in obstetrics, demand for the large majority of admissions is determined by the birth rate.[3]

In support of deregulation, the letter from Doctors Community Hospital, North Arundel Hospital, Suburban Hospital, and the University of Maryland Medical System describes the benefits of additional obstetrics providers as improvements in choice and access. They state that the public values more choice, and that more choice will result in more competition. In turn, more competition will force hospitals to respond to consumer preferences such as better quality, lower prices and more amenities. The joint letter suggests that new programs would produce savings for the community in the form of lower rates.

Two commenters, Anne Arundel Medical Center and Greater Baltimore Medical Center, indicate that any restructuring of the CON process that results in significant changes in obstetric admissions could jeopardize commitments made to HSCRC regarding debt costs for capital projects associated with obstetric service projects – often called 'the pledge'. According to the comments, these hospitals relied on reasonable forecasts of admissions when agreeing that the capital costs associated with major capital expenditures would not be included in future rate increases. The hospitals suggest that any deregulation option would require some relief from that commitment not to increase rates to pay for debt costs from the loss of those volumes.

Other comments state that, in the absence of increased demand, new programs could result in the reallocation of existing volumes, with significant financial impact on the system (DHS; JHHS). Several comments state that new programs would lead to higher system costs, particularly due to the unique additional capital facilities expenditures, the pressure on existing providers to compete with additional expenditures of their own, staffing costs compounded by increasing staffing shortages, duplication of resources and the additional staffing needs for neonatologists (CCGH; JHHS; LBH). The shortage of nursing and other professionals is expected to increase, resulting in rising staffing costs and jeopardizing cost effectiveness (DHS; JHHS). Nurses are already in short supply, adding direct staffing costs and indirect overhead to the system. As competition for specialized staff increases, labor costs will rise (DHS).

Commenters also suggest that, because obstetric services must be staffed to meet peak demand, system and individual facility efficiencies could drop by adding additional programs, which would increase systemwide costs (CCGH; DHS; HCH; LBH). As a result of obstetric services' unique staffing issues, several comments state that cost is directly linked to volumes. They state that obstetrics is a high fixed cost service, requiring full coverage 24 hours per day, seven days per week. They explain that because expenses, both for overhead and personnel, are almost wholly fixed, variable staffing is not possible. Thus costs go up directly with decreasing volumes (AAMC; GBMC; DHS). Not only will this will create higher costs for the public, this will create huge costs for existing hospitals

[3] Demand in a region or at a specific facility is influenced by many factors, including birth rates, rates of other types of obstetric admissions (described in the working paper), length of stay, migration patterns, physician referral patterns, and the availability and use of birthing centers.

that treat a disproportionate number of high-risk or safety net populations (DHS; HCH; LBH). Thus, according to some comments, the cost of adding additional capacity would not be in the best interests of the community (HCH).

Johns Hopkins Health System states that deregulation would allow hospitals to more easily exit the market, which may raise access issues, and concern for vulnerable populations with limited transportation options. Carroll County General Hospital suggests that quality issues arise from the spreading of volumes to more providers, given the effect of projected decreased volumes and underutilized or less experienced staff. In summary, the comments state that deregulation would increase the strain on resources given the current statewide and national nursing shortage, continued pressure from payers, and expected future capital needs.

Consistent with the way the HSCRC has set rates for new services, or cost centers, in the past, they would set rates for new obstetric, labor and delivery and nursery cost centers based on the statewide median for those cost centers. Staff agrees that, to the extent that patients at the new programs would have otherwise gone to a higher cost obstetrics service, and that the rates at the new program in other relevant cost centers (such as lab, radiology, pharmacy) were also lower, charges to payers would likely go down as suggested by the joint letter, at least temporarily. As noted in the working paper, the comments of other providers and the comments of the Health Services Cost Review Commission, given the level of competition currently existing in the hospital obstetrics market, it is difficult to imagine significant additional benefits that have not already been put forward.

The major advantage of deregulation cited by commenters is to allow any hospital to become 'full service' if it so chooses. Other potential advantages of deregulation noted in the public comments include more choice for patients, consistency with efforts to reduce regulation, more pressure on nearby existing providers to improve services, an opportunity to provide a lower cost option, or conversely an opportunity to provide a more amenities in comparison to existing obstetric services.

However, staff believes that a more complete economic analysis must include consideration of several factors. First, new providers could attract patients away from lower cost hospitals as well as higher cost hospitals, particularly if improved amenities affected consumer preferences. This would have the opposite effect from that suggested by the joint letter. Second, as hospital costs continue to rise, and to the extent that hospital rates are adjusted to reflect those increased costs, all the factors that make up increasing costs are included in the rate review. This could include increased costs of staffing as hospitals increase competition for limited nurses among more providers, and additional staffing in other areas such as neonatologists, and increased costs of capital improvements to provide the amenities needed to attract patients.

Staff believes that the comments from HSCRC do not support the conclusion that adding new obstetric service providers would necessarily result in a decline in charges. The HSCRC states that as hospitals compete for patients, their charges do not always

reflect their true costs. The HSCRC indicates that it may not allow this to continue if the hospitals are in jeopardy of cost shifting. In their comments the HSCRC states:

> "The Commission has, in particular, held down rates at certain hospitals for obstetric services. When these charges were later rate realigned, charges should have been significantly higher, based on the hospital's costs. Further, some hospitals are undercharging their HSCRC approved rate for obstetric services to avoid a payer shift of patients to lower cost hospitals.. while it would appear that hospital rate regulation addresses the issue of higher costs, these losses do not simply disappear, but are rather added back into the expenses of the state's overall health care system. This evidence would validate the working paper's observation that 'declining volume at existing services…combined with increased competition for staff and state-of-the-art facilities could increase costs at existing providers and/or the state's health care system.'"

The comments in the joint letter state that low volumes are not tied to inefficiencies or high charges. They note that the working paper shows that nine of the ten lowest volume hospitals have charges below the State's average obstetric charge per case. However, this appears to be explained by the comments from the HSCRC, which state that hospitals with lower volumes in obstetric services are not cost effective in that particular cost center, and that the HSCRC has held down charges for certain hospitals for obstetric services. Their higher obstetric costs are absorbed by the institution. The HSCRC also states that some hospitals are undercharging their approved rates to avoid a payer shift of patients to lower cost hospitals. Apparently the pressure of competition is significant enough that charges do not always reflect costs.

The joint letter also indicates they do not believe that deregulation of obstetrics from CON could strain the economic balance of existing Maryland hospitals, stating that this statement is not supported by any convincing logic or facts. However, HSCRC comments support the working paper's observation that declining admissions, and increased competition for both staff and facilities, could increase costs at existing providers and potentially throughout the State's health care system.

In conclusion, staff believes that the disadvantages of complete deregulation are the potential for increased costs to the system. Proliferation of additional providers leads to additional capital expenditures for new infrastructure including facilities, laboratory improvements, and staffing. As the working paper describes, obstetrics, as with most hospital inpatient services, is not a growing service. New providers mean declining volumes elsewhere, resulting in possible increased fixed cost allocations. The current staffing shortages means increased competition for fewer qualified staff and increased salary expenses. In addition, no significant improvement in access will result since current availability far exceeds established access standards.

Staff believes that Maryland's CON program has controlled the number of hospitals and hospital services, approving new facilities and services based on a public process requiring demonstrations that the advantages to access, cost effectiveness, and quality of

proposed new capacity outweigh disadvantages of added costs to the system. Although this role still predominates, CON is increasingly used to oversee rational downsizing, so that access is not reduced to insufficient levels, and that new expenditures are made wisely.

Finally, staff believes that, because demand is declining, but capacity is still at a peak, providers find themselves with declining occupancy and declining revenues. Many hospitals are searching for ways to survive in order to continue their community service mission. From a system perspective, not all hospitals should or will survive. It has long been recognized that a system with fewer hospitals and higher occupancy is more cost effective. Individual hospitals are rarely able to make these types of decisions. The Commission's statute reflects that merged hospital systems can do a better job, and foster some of the system downsizing. State oversight of this downsizing, currently done through the CON program, will help assure that access to needed services is not reduced inappropriately, and that certain critical individual hospital decisions are not inconsistent with the overall public interest. Staff believes that the major advantage of the CON program is the opportunity for an independent review of how certain actions affect the whole system of health care, thus providing some level of accountability that proposed new services are in the public interest and needed in terms of access, quality and cost effectiveness.

B. Option 2 – Expand Certificate of Need Program Regulation

The working paper's option to require Commission review and approval of service closures, rather than simple notification of closures, was proposed as a means to assure that access would not be significantly reduced by closures even in Maryland's four multiple hospital jurisdictions. Comments from MedStar Health state that existing regulations provide sufficient notice for achieving the public policy goal of timely notification. In their view, this additional oversight would result in delays and give false hopes of reversing inevitable closure decisions in financially distressed hospitals. They state that the public interest in these four jurisdictions is served by being given timely notification to provide for an orderly transition to other available options.

C. Option 3 – Maintain Existing Certificate of Need Program Regulation, With Regional Need Projection.

Bed or service need is currently projected on a jurisdictional basis for standard hospital services of medical surgical/gynecology, pediatrics, and obstetrics. Regional projections are done for acute psychiatry, open heart surgery, and organ transplants. One option included in the working paper proposed replacing jurisdictional need projections for obstetric services with regional need projections. Although merged hospital systems are able to reallocate services among member hospitals without a CON, reallocations must not be inconsistent with the State Health Plan, including the need projections. The implication of this option would be to eliminate the State Health Plan's restriction on merged hospital systems relocating services where no additional need is projected. If implemented, a system with an obstetrics program in one jurisdiction could move beds to

another system hospital in a different jurisdiction, within the same region, after a finding by the Commission.

Several commenters believe the Commission cannot justify changing the obstetric service need projections to redefine as a regional service one that is clearly a local service. Obstetric referrals are generally local and do not meet criteria used to justify planning specialized health services on a regional basis (MSH). CCGH suggests that obstetrics is not a regionalized service, stating that sufficient volumes exist in each jurisdiction to support the service. Over 90 percent of deliveries at JHHS' three hospitals are for patients in the immediate service area surrounding the hospital. The use of regional need calculations is not consistent with the distinctly local nature of obstetrics services (AAMC; GBMC). This option would benefit only one or two hospital systems, rather than patients, and has no merit (AAMC; GBMC). Other commenters argue that, although it may be justifiable to move obstetric services, this option would further private institutional objectives that could be counter to the public's interest (MSH).

DHMH's Center for Maternal and Child Health and LifeBridge Health agreed with the concept of regional rather than jurisdictional need projections. This is based on observed migration patterns that may cross jurisdictional, regional and even State boundaries, and the need to consider this migration data. However, these migration patterns are already considered in the State Health Plan's need projection methodology.

LifeBridge Health would support this option, with one significant change. LBH believes that merged asset systems can offer ways to improve efficiency, access and quality, and respond to changing demographics by relocating services between system facilities. They believe that services not be duplicated when responding to such needs. Therefore, a system should be permitted to relocate a service without a CON approval *only if it moves the entire service*, and not split an existing service into two or more parts.

Several comments suggest that this option is an expansion of the merger and consolidation exemption and is inconsistent with the General Assembly's intent, as expressed in HB 994 (1999) (AAMC; CCGH; GBMC). However, staff believes that this view is a misreading of a particular provision of HB 994, and a misinterpretation of legislative intent, which favors giving merged hospital systems significant flexibility with a minimum of administrative process. The provision of HB 994 often incorrectly cited as precluding the movement of beds across county lines by a merged system, if that creates a new service, only prevents this from occurring through a 45-day notice letter to the Commission. The statutory language is specific: "A hospital may not create a new health care service through the relocation of beds from one county to another county *pursuant to this subsection*." [Health-General Article 19-123(i)(2); emphasis added]. Commission statute governing CON review permits a change in the "type or scope of health care services' offered by a health care facility if the Commission finds, "in its sole discretion" that the proposed change is:

- pursuant to a consolidation or merger;

- is not inconsistent with the State Health Plan (or an institution-specific plan developed by the Commission);
- will result in the delivery of more efficient and effective health care services; and
- is in the public interest. [H-G 19-123(j)(3)(iv)

Thus, if the State Health Plan projects need for a service on a regional basis, and if other SHP standards are met by a proposed relocation of beds that creates a new service at the receiving system hospital, and the other three statutory tests are met, the Commission may approve that proposed change in type or scope of health services between two facilities in the same region but in different counties.

This finding by the Commission would require a CON exemption, as has been sought and granted to all proposed service reconfigurations between merged system members since 1985. The LifeBridge Health System, for example, received such an exemption in June 2000, for the relocation of twelve of Sinai Hospital's acute psychiatry beds to Northwest Hospital. This relocation would create a new service by moving beds across county lines.[4] Since the acute psychiatry need projection is regional, not jurisdictional, and LifeBridge sought and received a finding from the Commission, the relocation violates neither statutory provisions nor legislative intent, and received Commission approval.

D. Option 4 – Partial Deregulation from Certificate of Need Review- Create CON Exemption Process for New Obstetric Service

The working paper proposed elimination of the State Health Plan's need projections as a means to determine the need for new obstetric programs, while still retaining Commission's approval authority in market entry through an exemption from CON, rather than requiring CON approval to establish a new obstetric service. The exemption process has provided a more circumscribed public review process for those actions deemed desirable by the General Assembly, when certain specified favorable conditions present. Exemptions from the statutory requirement to obtain a Certificate of Need are available for certain actions that, without the presence of these conditions, would otherwise require a Certificate of Need. This option calls for the development of a new model of exemption that, for the first time, would apply to the development of new services, in this case obstetric services. The CON exemption process could then be used to assure that State Health Plan standards and criteria on access, cost and quality, which would need to be updated and further developed as part of Acute Inpatient Services chapter of the State Health Plan, would be met *before* implementation of a new obstetrics program. Criteria would likely address such issues as financial feasibility of the project, adequate staffing, impact on existing providers, and projected volumes.

AAMC's comments state that no sound policy reason related to concerns for access has been presented to justify elimination of the need projections. CCGH states that a

[4] Relocations of beds between system members when no new service is created is permitted with a 45-day notice letter.

CON exemption is subject to less stringent standards and interested parties have fewer procedural rights. The joint letter from Doctor's Community, North Arundel, Suburban and University of Maryland hospitals supports this option as an interim step to total deregulation. Their letter states that partial deregulation through elimination of need projections should be done in advance of passage of the legislation that would be required for Option 7, if it could be effectuated without a change in statute.[5]

Staff believes that the acceptability of this option will depend on the applicable criteria developed in the State Health Plan. Although this option raises some of the same issues of deregulation, it also potentially retains most of the advantages of the Certificate of Need program. In addition, in hospital obstetric services where there is little available literature or professional concern regarding a volume-outcome relationship as in certain specialized services, this option could set the stage for the development of innovative changes to regulatory oversight in response to the changing health care environment. Although a statutory change would be required to implement this option, the Commission can begin to identify review criteria along with other planned updates to the Acute Inpatient Services chapter of the SHP.

CON has provided for appropriate access without excessive over-building during the 'cost containment era'. Now, as the health care industry evolves again in the era of managed care, staff believes that new models of regulatory oversight should be explored. This option would potentially allow the Commission to provide for appropriate access while overseeing the complex aspects of system downsizing in an unstable market.

E. Option 5 – A Data Reporting Model to Replace Certificate of Need Regulation and Option 6 – Licensure Standards to Replace Certificate of Need Regulation

The working paper proposed three options suggesting total elimination of the CON program, two of them described possible replacement mechanisms that have different goals and objectives than the CON program. The implications are the same as described above under Option 7.

Three commenters support the concept of service-specific licensure as a replacement for CON regulation described in Option 6.[6] They feel that issues affecting quality of care are generally better served through licensing than through CON (AAMC; GBMC; SAH). GBMC and AAMC also state that licensure should be examined in greater detail, and considered if it would improve access, cost effectiveness, and/or quality of care.

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[5] As the working paper states, this option would require a statutory change. There are two reasons for this. First, as suggested in the working paper, the precedent of allowing for the first time the establishment of a new medical service through the exemption process rather than the CON process is significant. Second, it would require a statutory change because obstetrics is one of the 'medical services' listed in §19-123(j), as requiring a CON to establish. Also, in that same section, obstetrics would need to be added as a new medical service that could be established through an exemption finding by the Commission.

[6] There were no specific comments on Option 5.

SAH suggests that eliminating CON regulation and adopting a service-specific licensure approach will enable hospitals to respond to the needs of their patient population, and also afford the Commission a much improved quality monitoring and enforcement mechanism. Specifically, SAH proposes:

1) Deregulate obstetric services from CON;
2) Adopt the Perinatal Clinical Advisory Committee's guidelines as licensure standards;
3) Establish minimum volume thresholds as a quality standard for operating an obstetric service,
4) Establish performance standards and outcomes from morbidity and mortality data;
5) Require mandatory reporting of hospital-specific outcomes; and
6) Require programs to meet established performance standards benchmarks or lose licensure status.

HCH states that replacing the planning process with licensure can easily lead to gross proliferation of unnecessary services and increased system costs. AAMC and GBMC state that quality of care would not diminish if licensure replaced CON for obstetric services. They also indicate that the kinds of standards to be imposed would determine whether quality of care would be improved by a licensure system Carroll County General states that there is no evidence that deregulation with replacement by licensure would better serve the Commission's goal of ensuring access to quality health care services at a reasonable cost.

As noted by HCH, licensure already currently exists through DHMH's Office of Health Care Quality for hospitals, and through the Board of Physician Quality Assurance for physicians, the Board of Nursing for nurses, the Maryland Institute for Emergency Medical Services Systems for perinatal referral system designations, and through the Maryland Insurance Administration for insurers. HCH states that licensure alone, as a retrospective tool only, is insufficient to match services with the defined needs of a population. Service-specific licensure may be appropriate to regulate quality in some cases, but it is not an adequate substitute for CON (MSH). HCH and MSH state that licensure cannot answer the fundamental question of quality, which is whether services are needed. Licensure programs do not have the opportunity to address this question, although it is as fundamental to the question of quality as it is to the question of cost effectiveness. Staff believes that if unrestricted market entry would produce a net advantage to patients, and if the quality of care provided had been identified as a significant issue, replacing CON with licensure of obstetrics services may be an attractive option. While available data does not suggest that this is the case, staff remains open to additional information and discussion on this issue.

IV. Staff Recommendation

The issues identified in the working paper and further discussed in the public comments are complicated, and compelling arguments are made on both sides of the policy debate on the regulation of hospital obstetrics services. When evaluating the role of government and the role of specific regulatory mechanisms such as the CON program in hospital obstetric services, staff believes that Option 4 may represent the best potential solution for the State's broad policy objectives. Option 4, partial deregulation of obstetric services, would modify the current approach to regulation of market entry for obstetric services. This calls for a different model for regulating the development of new hospital obstetric services, while still retaining some authority and policy oversight with respect to the issues of access, quality, and cost effectiveness.

Therefore, the Commission should direct staff to develop a model of Certificate of Need exemption governing the development of new obstetric services, including necessary statutory and regulatory changes, possible criteria and standards for review of potential new programs, the role of the State Health Plan's need projections, and implications for proposals not qualifying for exemption, being mindful of the public interest as well as the need to guide certain critical hospital decisions.

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